

## **REMARKS**

### **I. Introduction**

By the present amendment, claims 1, 23, and 24 have amended. No claims have been added or canceled. Accordingly, claims 1, 3, 6-20, 23, and 24 remain pending in the application. Claims 1, 23, and 24 are independent.

### **II. Interview**

Applicants would like to thank Examiners Brutus and Chen for the courtesy and cooperation extended during the interview conducted on January 12, 2011. During the interview, Applicants discussed proposed amendments to the independent claims which were intended to define over the art of record. Applicants indicated that the manner in which the calculation means calculates the distance between the first boundary and the second boundary to obtain the composite thickness of the tunica intima and the tunica media was not disclosed by the art of record. The Examiner indicated that further review of the references would be necessary to confirm applicants interpretation. Additionally, further searching and consideration would likely be necessary in view of the newly added limitations.

### **III. Office Action Summary**

In the Office Action of April 29, 2010, claims 1, 3, 6-9, 12, 13, 18, 20-22, and 24 were rejected under 35 USC §103(a) as being unpatentable over U.S. Patent No. 6,132,373 issued to Ito et al. ("Ito '373"). Claims 10, 11, 15-17, 19, and 23 were rejected under 35 USC §103(a) as being unpatentable over Ito '373 in view of U.S. Patent No. 5,353,220 issued to Ito et al. ("Ito '220"). Claim 14 was rejected under 35

USC §103(a) as being unpatentable over Ito '373 in view of U.S. Patent No. 5,615,680 issued to Sano. These rejections are respectfully traversed.

#### **IV. Rejections under 35 USC §103**

Claims 1, 3, 6-9, 12, 13, 18, 20, and 24 were rejected under 35 U.S.C. §103(a) as being unpatentable over Ito. Regarding this rejection, the Office Action indicates that Ito discloses an apparatus for measuring an intima-media thickness of a blood vessel, a data analyzing device for receiving image data and calculating the intima-media thickness of the blood vessel according to the image data, and that the digital data includes a plurality of luminance values that each correspond to respective ones of a plurality of pixels of the image. The Office Action states that Ito discloses a calculation device for detecting maximum value and a minimum value from among the luminance values in order calculate the intima-media thickness, a thickness calculation device that includes 1 to 5 detection devices for detecting the maximum and minimum values of luminance, and a data analyzing device.

The Office Action admits that Ito fails to disclose a setting range that includes tunica intima reference points or a tunica externa reference point so that the brightness falls within the setting range, or the distance between boundaries and the blood vessel wall. Nonetheless, the Office Action indicates that Ito discloses a predetermined range of pixels due to changes in the location of the inner intimal wall and inner adventitial wall relative to the Z-axis direction being expressed with regression curves. The Office Action also indicates that Ito discloses the calculation device calculating a difference between a value representing the position of an inner intimal wall and a value representing the position of an inner adventitial wall, and measuring the borders between the various walls. The Office Action concludes that

it would have been obvious to calculate a distance between the two borders in a region based on the reference points. Applicants respectfully disagree.

As amended, independent claim 1 defines a medical imaging diagnostic apparatus that obtains image data from a blood vessel of an object being examined and measures the composite thickness of a tunica intima and a tunica media of the blood vessel. The medical imaging diagnostic apparatus comprises:

brightness distribution acquisition means for acquiring a brightness distribution in the thickness direction of a blood vessel wall in a tomogram with regard to the blood vessel,

setting means for setting the tunica intima reference point and the tunica externa reference point based on the brightness distribution,

extraction means for extracting pixels, with respect to each pixel in a setting range including the tunica intima reference point or the tunica externa reference point, wherein the brightness belongs to the setting range, and

calculation means for calculating a first boundary in the lumen side between an intravascular lumen and an end of a region formed by the pixels being extracted, calculating a second boundary in the lumen side in a region formed by the pixels being extracted based on the tunica externa reference point, and calculating a distance between the first boundary and the second boundary by interpolating the composite thickness of the tunica intima and the tunica media.

Independent claim 1 defines a medical imaging diagnostic apparatus that includes a brightness distribution acquisition means which acquires the brightness distribution in the thickness direction of a blood vessel wall in a tomogram with respect to the blood vessel, and a setting means which sets the tunica intima reference point and the tunica externa reference point based on the brightness distribution. An extraction means is provided for extracting pixels in the setting range including the tunica intima reference point or the tunica externa reference point wherein the brightness belongs to the setting range. According to independent claim 1, the medical imaging diagnostic apparatus also includes a calculation means for

calculating a first boundary in the lumen side between an intravascular lumen and an end of a region formed by the pixels being extracted, and calculating a second boundary in the lumen side in a region formed by the pixels being extracted based on the tunica externa reference point. The calculation means also calculates a distance between the first boundary and the second boundary by interpolating the composite thickness of the tunica intima and the tunica media.

As discussed in the Specification, a calculation means (30) is provided for calculating the distance between the boundary in the blood vessel wall side in the region formed by the pixels extracted based on the tunica intima reference point (the inner wall of the tunica intima) and the boundary in the lumen side in the region formed by the pixels extracted based on the tunica externa reference point (the inner wall of the tunica externa). See paragraph [0053] of the published application and Fig. 1. Additionally, the medical imaging diagnostic apparatus includes a brightness distribution acquisition means (25), setting means (26), and extraction means (28). Referring to Figs. 3 and 4, the pixels corresponding to tunica intima (SP42) are extracted by the extraction means (28) at steps S111 and S112, thereby forming an extracted region (58). The boundary on the side of the lumen (40) of the extracted region (58) corresponds to the inner wall (60) of the tunica intima (42). See paragraph [0064]. The calculation means (30) calculates the coordinate data corresponding to the inner wall (60) and stores it as positional data of the inner wall (60) of the tunica intima (42) at step S116. See paragraph [0065]. The calculation means (30) then determines the distance between the inner wall (60) of tunica intima (42) and inner wall (62) of tunica externa (46) based on the positional data of the inner wall (60) of the tunica intima (42) stored at step S116 and the positional data of

the inner wall (62) of the tunica externa (46) being stored at step S124. See paragraph [0069].

The Office Action alleges that Ito '373 discloses all of the features recited in independent claim 1. This does not appear to be the case. Ito discloses an apparatus for measuring the intima-media thickness of a blood vessel wherein an ultrasound device is provided for outputting digital image data representing an image of the blood vessel produced by scanning with an ultrasound. A data analyzing device is provided for receiving the output digital image data and calculating the intima-media thickness of the blood vessel according to the received digital image data. Ito further indicates that points Xa and Xb, from which the curve rises to the peak values, are regarded as points indicating the locations of the inner intimal and adventitial walls. The point Xb from which the curve rises up to the largest peak value which indicates a position on the adventitia is regarded as the location of the inner adventitial wall. The point Xa from which the curve rises up to the second largest peak value which indicates a position on the intima is regarded as the location of the inner intimal wall.

As discussed in the Background Section of the application, however, Ito '373 (JP-A-99-318896) operates differently from the present invention. In conventional ultrasound apparatus for measuring intima media thickness, such as the one disclosed in Ito '373, the brightness distribution in the thickness direction of a blood vessel wall of image data in one line is obtained. The local maximal point having the maximum brightness of the brightness distribution is then set as tunica externa reference point A. The second local maximal point that appears from tunica externa reference point A in the lumen side is set as tunica intima reference point B. The intima media thickness measurement is subsequently performed by setting a

minimum point C that appears in the lumen side from tunica media reference point B as the inner wall of the lumen, as well as setting the midpoint between point D having the minimum brightness of the brightness distribution and tunica externa reference point A as the inner wall of the lumen. See paragraph [0004] of the published application. Thus, according to Ito '373, the tunica externa reference point and tunica intima reference point are set based on the brightness distribution in the thickness direction of the blood vessel wall based on one line of acquired image data. The intima media thickness measurement is subsequently performed in each line based on the tunic externa reference point and tunica intima reference point.

At least one problem associated with such techniques is that the minimum point C does not always appear clearly in the lumen side from the tunica media reference point in the brightness distribution of image data. Additionally, the midpoint between point D and tunica externa reference point A is set as the inner wall position of the tunica externa based on empirical rules obtained from factors such as clinical results. Due to the individual variability of objects being examined, there are cases that IMT cannot be measured accurately by utilizing the techniques disclosed by Ito '373. See paragraph [0006].

In contrast, the present invention extracts both a region of the tunica intima and a region of the tunica externa, and measures the IMT based on the inner end of the extracted region of the tunica intima in the radial direction of the blood vessel and the inner end of the extracted region of the tunica externa in the radial direction of the blood vessel. According to such features, it become possible to accurately measure the IMT despite any individual variability of objects being examined. Review of Ito '373 has failed to reveal any disclosure or suggestion for such features.

It is therefore respectfully submitted that independent claim 1 is allowable over the art of record.

Claims 3 and 6-20 depend from independent claim 1, and are therefore believed allowable for at least the reasons set forth above with respect to independent claim 1. In addition, these claims each introduce novel elements that independently render them patentable over the art of record.

As amended, independent claim 24 defines a medical imaging diagnostic method that comprises:

- acquiring a brightness distribution in the thickness direction of a blood vessel wall in a tomogram with regard to the blood vessel,

- setting a tunica intima reference point and a tunica externa reference point based on the brightness distribution,

- extracting pixels, with respect to each pixel in a setting range including the tunica intima reference point or the tunica externa reference point, wherein the brightness belongs to the setting range,

- calculating a first boundary in the lumen side between an intravascular lumen and an end of a region formed by the pixels being extracted,

- calculating a second boundary in the lumen side in a region formed by the pixels being extracted based on the tunica externa reference point, and

- calculating a distance between the first boundary and the second boundary by interpolating the composite thickness of the tunica intima and the tunica media.

The medical imaging diagnostic method of independent claim 24 recites various steps that correspond to actions performed by the elements recited in independent claim 1. As previously discussed, Ito '373 calculates the intima media thickness in a manner that differs from that of the present invention.

It is therefore respectfully submitted that independent claim 23 is allowable over the art of record.

Claims 10, 11, 15-17, 19, and 23 were rejected under 35 USC §103(a) as being unpatentable over Ito '373 in view of "Ito '220. As previously discussed, claims 10, 11, 15-17, 19, and 23 depend from independent claim 1 and are therefore believed to be allowable over the art of record.

Regarding claim 23, the Office Action asserts that Ito '373 discloses most of the features recited therein, except for three dimensional image data and Doppler imaging. Ito '220 is relied upon for disclosing a color three dimensional Doppler image data, wherein flow in a blood vessel is adopted as the object and a 3D color Doppler image is displayed by respective color reconstruction. The Office Action concludes that it would have been obvious to combine the two Ito references to obtain the tunica intima for the purpose of measuring the intima media thickness more accurately. Applicants respectfully disagree.

As amended, independent claim 23 defines a medical imaging diagnostic apparatus that comprises:

imaging means for obtaining image data related to a blood vessel of an object being examined;

Doppler imaging means for obtaining color Doppler image data related to the blood vessel;

brightness distribution acquisition means for acquiring the brightness distribution in the thickness direction of the blood vessel wall of the color Doppler image data;

setting means for setting the tunica intima reference point and the tunica externa reference point based on the brightness distribution;

extraction means for extracting the pixels, with respect to each pixel in the setting range including the tunica intima reference point or the tunica externa reference point, wherein the brightness belongs to the setting range; and

calculating means for calculating a first boundary in the lumen side between an intravascular lumen and an end of a region formed by the pixels being extracted, calculating a second boundary in the lumen side in a region formed by the pixels being extracted based on the tunica externa reference point, and calculating a distance between the

first boundary and the second boundary by interpolating the composite thickness of the tunica intima and the tunica media.

The medical imaging diagnostic apparatus of independent claim 23 includes an imaging means for obtaining image data related to a blood vessel or an object being examined, a Doppler imaging means for obtaining color Doppler image data related to the blood vessel, and a brightness distribution acquisition means for acquiring the brightness distribution in the thickness direction of the blood vessel wall of the color Doppler image data. A setting means is provided for setting the tunica intima reference point and the tunica externa reference point based on the brightness distribution, and an extraction means is provided for extracting the pixels with respect to each pixel in the setting range including the tunica intima reference point or the tunica externa reference point, wherein the brightness belongs to the setting range. The medical imaging diagnostic apparatus further includes a calculating means for calculating a first boundary in the lumen side between an intravascular lumen and an end of a region formed by the pixels being extracted, calculating a second boundary in the lumen side in a region formed by the pixels being extracted based on the tunica externa reference point, and calculating a distance between the first boundary and the second boundary by interpolating the composite thickness of the tunica intima and the tunica media.

As previously discussed with respect to independent claim 1, such features are not shown or suggested by the art of record. Furthermore, review of Ito '220 has failed to reveal any disclosure or suggestion for the features, such as the calculating means, that are lacking from Ito '373.

It is therefore respectfully submitted that independent claim 23 is allowable over the art of record.

**V. Conclusion**

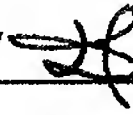
For the reasons stated above, it is respectfully submitted that all of the pending claims are now in condition for allowance. Therefore, the issuance of a Notice of Allowance is believed in order, and courteously solicited.

If the Examiner believes that there are any matters which can be resolved by way of either a personal or telephone interview, the Examiner is invited to contact Applicants' undersigned attorney at the number indicated below.

**AUTHORIZATION**

Applicants request any shortage or excess in fees in connection with the filing of this paper, including extension of time fees, and for which no other form of payment is offered, be charged or credited to Deposit Account No. 01-2135 (Case: 529.46525X00).

Respectfully submitted,  
ANTONELLI, TERRY, STOUT & KRAUS, LLP.

/Leonid D. Thenor/   
Leonid D. Thenor  
Registration No. 39,397

LDT/vvr  
1300 N. Seventeenth Street  
Suite 1800  
Arlington, Virginia 22209  
Tel: 703-312-6600  
Fax: 703-312-6666

Dated: February 22, 2011